DEPARTMENT OF CONSUMER AND INDUSTRY SERVICES

DIRECTOR'S OFFICE

CONTROLLED SUBSTANCES

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These rules take effect 7 days after filing with the Secretary of State.

(By authority conferred on the director of the department of consumer and industry services by 1978 PA 368 and Executive Reorganization Order No. 1996-2, MCL 333.7201, 333.7301, 333.7333, 333.7333a, 333.16145, and 445.2001)

R 338.3101, R 338.3102, R 338.3104, R 338.3161,R 338.3162, R 338.3164, R 338.3165, R 338.3166, R 338.3167, and R 338.3168 of the Michigan Administrative Code are amended, and R 338.3162b, R 338.3162c, R 338.3162d, and R 338.3162e are added to the Code as follows:

PART 1. GENERAL PROVISIONS

R 338.3101 Definitions; A to E.

Rule 1. As used in these rules:

(a) "Act" means 1978 PA 368, MCL 333.1101 et seq.

(b) "Deleterious drug" means a drug, other than a proprietary medicine, that is likely to be destructive to adult human life in quantities of 3.88 grams or less.

(c) "Department" means the Department of Consumer and Industry Services.

(d) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record. An electronic signature also is a unique identifier protected by appropriate security measures such that it is only available for use by the intended individual and ensures nonrepudiation so that the signature could not be rejected based on its validity.

R 338.3102 Definitions; I to P.

Rule 2. (1) As used in these rules:

(a)“Inventory” means all stocks in finished form of a controlled substance that is manufactured or otherwise acquired by a licensee, whether in bulk or commercial containers or contained in pharmaceutical preparations in the possession of the licensee.

(b) “Licensee” means a person who is licensed pursuant to section 7303 of the act.

(c) “Michigan automated prescription system (maps) claim form” means a form, to be determined by the department, that is in the format and includes the information as specified by the american society for automation in pharmacy (asap) and contains the information specified in R 338.3162b.

(d) "National drug code number (ndc)” means an 11-digit, 3-segment number that identifies the labeler/vendor, product, and package size and is assigned to each drug product listed under section 510, registration of producers of drugs and devices, of the federal food, drug, and cosmetic act.

(e) “Officer” means a state, county, or local law enforcement officer who has a duty to enforce the laws of this state.

(f) “Patient identifier” includes the following information about a patient:

(i) Full name.
(ii) Address, including zip code.
(iii) Date of birth.
(iv) Any of the following:
  (A) Social security number.
  (B) Driver’s license number.
  (C) State-issued identification number.
(v) If a patient is an animal, any of the following:
  (A) The owner’s social security number.
  (B) The owner’s driver’s license number.
  (C) The owner’s state-issued identification number.

(g) “Prescriber” or “practitioner” means any of the following individuals who are licensed to prescribe by the laws of this state:

(i) A dentist.
(ii) A doctor of medicine.
(iii) A doctor of osteopathic medicine and surgery.
(iv) A doctor of podiatric medicine and surgery.
(v) A veterinarian.

(2) As used in part 5 of these rules:

(a) “Medical institution” means an inpatient health facility which is licensed or approved by the state and which directly or indirectly provides or includes pharmacy services.

(b) “Pharmacy services” means the direct and indirect patient care services associated with the practice of pharmacy.

R 338.3104 Definitions; R, S.

Rule 4. As used in these rules:

(a) “Readily retrievable” means a record which is kept in such a manner that it can be separated from all other records within 48 hours and in which a listed controlled substance shall be marked with an asterisk, redlined, or in some other manner be visually identifiable apart from the other substances listed in the record.

(b) “Scientific investigator” means a person, other than a physician, who is licensed to conduct research with a controlled substance listed in schedules 1 to 5.

(c) “Sign” means to affix a signature manually in the same manner as signing a check or legal document or to use an electronic signature, as defined in subdivision (d) of R 338. 3101. Stamped signatures are not valid for any controlled substance prescription.

(d) “Substance” means a controlled substance unless the context indicates otherwise.

PART 6. DISPENSING AND ADMINISTERING PRESCRIPTIONS

R 338.3161 Prescriptions.

Rule 61. (1) A prescription that is issued for a controlled substance shall be dated and signed when issued and shall contain all of the following information:

(a) The full name and address of the patient for whom the substance is being prescribed.

(b) The prescriber's drug enforcement administration (dea) registration number, printed name, address, and professional designation.

(c) The drug name, strength, and dosage form.

(d) The quantity prescribed. For a prescription received in writing, the prescription shall contain the quantity in both written and numerical terms. A written prescription is in compliance if it contains preprinted numbers representative of the quantity next to which is a box or line the prescriber may check.

(e) The directions for use.

(f) In addition, if the prescription is for an animal, then the species of the animal and the full name and address of the owner.

(2) A written prescription for a controlled substance in schedules 2 to 5 shall be written with ink or an indelible pencil, or prepared using a printer and shall be signed by the prescriber.

(3) An agent of the prescriber may prepare a prescription for the signature of the prescriber, but, pursuant to the act, the prescriber is liable if the prescription does not conform to these rules. A pharmacist who

dispenses a controlled substance pursuant to a prescription not prepared in the form required by these rules is liable pursuant to the act.

(4) If the controlled substance prescription or order in a medical institution is issued pursuant to delegation under R 338.2304, R 338.2305, R 338.108a, or R 338.108b, then the printed name of the delegatee, the licensure designation, the delegating prescriber, and the signature of the delegatee shall be on the written prescription. In medical facilities, orders shall contain the signatures of the delegatee and the printed name of the delegating prescriber.

(5) A prescription shall not be issued by a prescriber to obtain a stock of a controlled substance for the purpose of dispensing or administering the substance to patients.

R 338.3162 Dispensing by pharmacists; delivery of controlled substances.

Rule 62. (1) A controlled substance shall be dispensed by a pharmacist or a pharmacy intern in the presence, and under the immediate supervision, of a pharmacist.

(2) A pharmacist may require identification of individuals to whom controlled substances are delivered.

(3) Except as provided by R 338.3162a, a pharmacist may dispense a controlled substance which is listed in schedules 3 to 5 and which is a prescription drug pursuant to the provisions of the federal food, drug, and cosmetic act of 1991, 21 U.S.C. §201.100(b)(i) et seq., only pursuant to a written, electronically transmitted, or oral order of a prescriber that contains all of the required information under R 338.3161, except that the signature of the prescriber is not required if the controlled substance is obtained pursuant to an oral order.

(4) If an oral order for a controlled substance listed in schedules 3 to 5 is transmitted by the prescriber's agent under delegation, then all of the following shall be recorded on the prescription generated at the pharmacy:

(a) The information required by R 338.3161.

(b) The transmitting agent's identity.

(c) The individual who received the prescription at the pharmacy.

(5) Only an order that is issued in the usual course of professional treatment or in the course of legitimate and authorized research is a prescription.

R 338.3162b Electronic system for monitoring schedules 2, 3, 4, and 5 controlled substances.

Rule 62b. (1) A pharmacist, dispensing prescriber, and veterinarian licensed under Part 177 who dispenses a prescription drug which is a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by the state that dispenses in this state or dispenses to an address in this state a controlled substance listed in schedules 2 to 5 shall report to the

department or the department's contractor by means of an electronic data transmittal process the following information for each prescription of a schedules 2 to 5 controlled substance prescription dispensed:

(a) The patient identifier, as defined in R 338.3102 (f).

(b) The name of the controlled substance dispensed.

(c) The metric quantity of the controlled substance dispensed.

(d) The national drug code number (ndc) of the controlled substance dispensed.

(e) The date of issue of the prescription.

(f) The date of dispensing.

(g) The estimated days of supply of the controlled substance dispensed.

(h) The prescription number assigned by the dispenser.

(i) The dea registration number of the prescriber and the dispensing pharmacy.

(j) The Michigan license number of the dispensing pharmacy.

(2) A pharmacist, dispensing prescriber, or veterinarian may presume that the patient identification information provided by a patient or a patient's representative is correct.

R 338.3162c Format for electronic transmission of data; waiver.

Rule 62c. (1) A pharmacist, dispensing prescriber, or veterinarian who dispenses a prescription drug which is a controlled substance listed in schedules 2 to 5 shall transmit the data, as specified under R 338.3162b, by one of the following methods:

(a) An electronic device compatible with the receiving device of the department or the department's contractor.

(b) A computer diskette.

(c) A magnetic tape or cartridge.

(d) Other medium, as approved by the department or the department's contractor.

(2) The data shall be transmitted in the format established by the american society for automation in pharmacy (asap) telecommunications format for controlled substances.

(3) A pharmacist, dispensing prescriber, or veterinarian who dispenses controlled substances and who does not have an automated record-keeping system capable of producing an electronic report in the format established by subrule (2) of this rule may request a waiver from electronic reporting. The request shall be made in writing to the department.

(4) A pharmacist, dispensing prescriber, or veterinarian may be granted a waiver, if he or she demonstrates an inability to report as required by R 338.3162b and he or she agrees in writing to report the data to the department or the department's contractor by submitting a completed maps claim form as defined in R 338.3102(c) or transmitting data via an internet web portal that is provided by the department or the department's contractor for this purpose.

R 338.3162d Required reporting of prescription data; error reporting.

Rule 62d. (1) A pharmacist, dispensing prescriber, or veterinarian shall report all schedules 2 to 5 controlled substances dispensed beginning on the date that these amendatory rules take effect.

(2) The data required by R 338.3162b shall be forwarded by on-line transmission computer diskette, magnetic tape or cartridge, or other approved medium as specified in R 338.3162c to the department or the department's contractor at least every 30 days and no later than the 15th calendar day of the month following the month in which the prescription is dispensed.

(3) For each pharmacist, dispensing prescriber, or veterinarian who does not have the capacity to forward the information as specified in R 338.3162b, the information shall be mailed or delivered to a location specified by the department or the department's contractor at least every 30 days and no later than the 15th calendar day of the month following the month in which the prescription is dispensed.

(4) The department or the department's contractor shall notify a pharmacist, dispensing prescriber, or veterinarian of an error in data reporting. Upon receiving notification of an error in data reporting, a pharmacist, dispensing prescriber, or veterinarian shall take appropriate measures to correct the error and transmit the corrected data to the department or the department's contractor within 15 days of being notified of the error.

(5) A pharmacist, dispensing prescriber, or veterinarian who fails to report the dispensing of a prescription for a controlled substance listed in schedules 2 to 5 as required, beginning on the date that these amendatory rules take effect, shall be subject to the penalty provisions in sections 16221, 17741, or 17768 in article 15 of the act.

R 338.3162e Exemption from reporting requirements.

Rule 62e. A pharmacist, dispensing prescriber, or veterinarian shall be exempt from the reporting requirements under the following circumstances:

(a) When a controlled substance in schedules 2 to 5 is administered directly to a patient.

(b) When a controlled substance in schedules 2 to 5 is dispensed from a health facility or agency licensed under article 17 of the act by a dispensing prescriber in a quantity adequate to treat a patient for not more than 48 hours.

R 338.3164 Emergency dispensing of schedule 2 substances; oral prescriptions.

Rule 64. A pharmacist may dispense a controlled substance listed in schedule 2 in case of an emergency in which all of the following conditions are met:

(a) The prescriber advises the pharmacist of the following:

(i) Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user.

(ii) Appropriate alternative treatment is not available, including administration of a drug that is not a controlled substance under schedule 2.

(iii) It is not reasonably possible for the prescriber to provide a written prescription to be presented to the person dispensing the substance before the dispensing.

(iv) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period and pursuant to a written prescription.

(b) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information that is required to be contained in a prescription under provisions of R 338.3161, except for the prescriber's signature.

(c) If the prescriber is not known to the pharmacist, then the pharmacist shall make a reasonable effort to determine that the oral authorization came from a prescriber by returning the prescriber's call, using the telephone number listed in the telephone directory and other good faith efforts to assure the prescriber's identity.

R 338.3165 Emergency dispensing of schedule 2 substances; written prescriptions.

Rule 65. Within 7 days after authorizing an emergency oral prescription of a controlled substance listed in schedule 2, the prescriber shall reduce the prescription to writing and have recorded on the prescription's face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription shall be delivered to the pharmacist in person or by mail within 7 days after the oral prescription is issued. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral order which earlier had been reduced to writing. The pharmacist shall notify the department of consumer and industry services if the prescriber fails to deliver a written prescription to him or her. The failure of a pharmacist to notify the department if the prescriber fails to deliver a written prescription voids the authority conferred by this rule to dispense without a written prescription of a prescriber.

R 338.3166 Partial dispensing of schedule 2 substances.

Rule 66. (1) A pharmacist may partially dispense a controlled substance listed in schedule 2 if he or she is unable to supply the full quantity called for in a written or emergency oral prescription and he or she makes a notation of the quantity supplied on the face of the written prescription or written record of the emergency oral prescription. The remainder of the prescription may be dispensed within 72 hours after the first partial dispensing. If the remainder of the prescription is not or cannot be dispensed within the 72 hours, the pharmacist shall so notify the prescriber. A further quantity shall not be dispensed beyond the 72 hours without a new prescription.

(2) Prescriptions for schedule 2 controlled substances that are written for a patient in long-term care facilities or for a patient with a medical diagnosis that documents a terminal illness may be filled in partial quantities, including individual dosage units. For each partial filling, the dispensing pharmacist shall record, on the back of the prescription or on another appropriate record that is uniformly maintained and readily retrievable, all of the following information:

(a) Date of the partial filling.

(b) Quantity dispensed.

(c) Remaining quantity authorized to be dispensed.

(d) Identification of the dispensing pharmacist.

The total quantity of schedule 2 controlled substances dispensed in all partial fillings shall not be more than the total quantity prescribed. Schedule 2 prescriptions for a patient in a long-term care facility or for a patient with a medical diagnosis that documents a terminal illness shall be valid for a period of not more than 60 days from the issue date unless terminated at an earlier date by the discontinuance of medication. A pharmacist shall record on the prescription whether the patient is terminally ill or is a long-term care facility patient.

R 338.3167 Dispensing schedule 5 substances without prescriptions.

Rule 67. (1) A pharmacist may, without a prescription, dispense a controlled substance listed in schedule 5 which is not a prescription medication as determined under the federal food, drug, and cosmetic act, 21 U.S.C. §§301 to 392, if all of the following provisions are met:

(a) The dispensing pharmacist has determined it is to be used for a medical purpose.

(b) Not more than 240 cc (8 ounces) or 48 solid doses of a substance containing opium or more than 120 cc (4 ounces) or 24 solid doses of any other substance listed in schedule 5 are distributed at retail to the same purchaser in any single 48-hour period.

(c) The purchaser is at least 18 years of age.

(d) The pharmacist requires a purchaser not known to the pharmacist to furnish suitable identification, including proof of age where appropriate.

(2) If a pharmacist dispenses a controlled substance listed in schedule 5, then he or she shall affix to the container in which the substance is dispensed a label that shows the date, his or her own name, and the name and address of the place of practice in which the substance is dispensed.

(3) The pharmacist shall maintain a record of the dispensing of controlled substances listed in schedule 5. The record shall be immediately retrievable and may be maintained in the same manner as required for schedule 5 prescription medication. The record shall contain all of the following information:

(a) The name and address of the patient.

(b) The name and address of the purchaser if different from the patient.

(c) The name and quantity of substance purchased.

(d) The date purchased.

(e) The name or initials of the pharmacist or pharmacy intern who dispensed the substance.

(f) The medical purpose for which the medication is being used as determined by the pharmacist.

R 338.3168 Refilling of prescriptions.

Rule 68. (1) A prescription for a controlled substance listed in schedule 2 shall not be refilled.

(2) A prescription for a controlled substance listed in schedules 3 and 4 shall not be refilled more than 6 months after the prescription's date of issuance and shall not be refilled more than 5 times. Renewal of the prescription shall be effected and recorded in the same manner as an original prescription.

(3) A partial filling of a controlled substance prescription in schedules 3, 4, and 5 is permissible if all of the following provisions are met:

(a) Each partial filling is recorded in the same manner as a refilling.

(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

(c) No dispensing occurs after 6 months after the date on which the prescription was issued for schedules 3 and 4.

(4) A prescription for a controlled substance listed in schedule 5 may be refilled only as expressly authorized by the prescriber on the prescription; if no authorization is indicated, then the prescription shall not be refilled.